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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,120	11/29/2004	Masaru Yamakoshi	1516-0126PUS1	3292
2292	7590	04/20/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			MARTIN, PAUL C	
			ART UNIT	PAPER NUMBER

1655

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/509,120	YAMAKOSHI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 18-24 and 27 is/are rejected.
- 7) ☒ Claim(s) 5-14, 25, 26 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/28, 11/24, 12/28/04</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-14 and 18-28 are pending in this application.

#### ***Election/Restrictions***

Applicant's election without traverse of Group I (Claims 1-14 and 18-28) in the reply filed on 03/03/06 is acknowledged.

Claims 15-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/03/06.

Claims 1-14 and 18-28 were examined on their merits.

#### ***Claim Objections***

Claims 5-14, 25, 26 and 28 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or, cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 5-14, 25, 26 and 28 not been further treated on the merits.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Larner (5,750,348).

Larner teaches a method for detecting mild impaired glucose tolerance by quantitatively determining myo-inositol levels in urine samples and evaluating cases where the level shows a characteristic value higher than control as impaired glucose tolerance or an insulin secretory defect (Column 2, Lines 5-60).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashizawa *et al.* (2000).

Ashizawa teaches a method for quantitatively determining myo-inositol in a tissue sample using the enzyme myo-inositol dehydrogenase and NADH in an enzymatic cycling method, (Pg. 90, Lines 1-11) and evaluating cases wherein the level shows a characteristic value in diabetic subjects (insulin secretion defective) (Pg. 93, Table 1).

Ashizawa teaches the use of ATP-hexokinase in order to remove glucose interference (Pg. 89, Abstract Lines 3-5 and Pg. 90, Lines 19-25).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 18-20 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashizawa *et al.* (2000) in view of Tazoe *et al.* (6,309,852).

The teachings of Ashizawa were discussed above.

Ashizawa does not teach a method wherein two kinds of kinase are used in combination, wherein the two kinds of kinase are ATP-hexokinase and an ADP-eliminating agent, or wherein the ADP-eliminating agent is ADP-hexokinase.

Tazoe teaches a method for the quantitative determination of 1,5-anhydroglucitol, a known marker for glycemic control in diabetic patients wherein the kinases ADP-dependent hexokinase and 6-phosphofructokinase are used in combination (Column 4, Lines 40-65).

Tazoe teaches that the removal of glucose using hexokinase results in the unfavorable formation of large quantities of ADP (Column 1, Lines 55-67)

Tazoe teaches the use of the buffers TEA and Tris (Column 9, Lines 13-19).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method for quantitatively determining the amount of myo-inositol in a sample using ATP-hexokinase to remove interfering glucose as taught by Ashizawa with the method of eliminating glucose interference using two kinds of kinase, one of which being ADP-dependent hexokinase as taught by Tazoe in order to remove the possible interference of glucose and ADP on the reaction.

One of ordinary skill in the art would have been motivated to combine the two methods in order to achieve the dual advantages of removing glucose interference by two overlapping means and simultaneously removing potentially interfering ADP accumulations as taught by Tazoe. There would have been a reasonable expectation of success based upon the fact that both methods use hexokinase and are drawn toward eliminating glucose interference and examining markers for glucose intolerance or insulin secretion defect markers.

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashizawa *et al.* (2000) in view of Tazoe *et al.* (6,309,852) further in view of Kozuma *et al.* (6,046,018).

The teachings of Ashizawa and Tazoe were discussed above.

Neither Ashizawa nor Tazoe teach the use of thio-NAD.

Kozuma teaches a method for the quantitative determination of chiro-inositol (a marker for insulin resistance) in a sample enzymatically using a dehydrogenase, in the presence of thio-NAD (Column 1, Lines 1-50).

Kozuma teaches that previously known myo-inositol and inositol dehydrogenases would not catalyze reaction using thio-NAD and thus would not be useful for enzyme cycling reactions using NAD and thio-NAD (Column 2, Lines 28-45), and teaches a new inositol dehydrogenase that will catalyze thio-NAD and NAD (Column 3, Lines 4-26).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method for quantitatively determining the amount of myo-inositol in a sample using ATP-hexokinase to remove interfering glucose as taught by Ashizawa with the methods of eliminating glucose interference using two kinds of kinase, as a means of eliminating potentially interfering amounts of ADP. One of ordinary skill in the art at the time of invention would have been motivated to combine the three methods in order to achieve the advantages of removing glucose interference by two overlapping means and simultaneously removing potentially interfering ADP accumulations, as well as achieving a highly specific, simple and low-cost assay for determining myo-inositol as taught by Ashizawa. There would have been a reasonable expectation of success based on the similarity between the methods (being drawn to characterizing diabetes markers) and their overlapping use of similar materials.



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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**No Claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin  
Examiner  
Art Unit 1655

04/05/06

  
TERRY MCKELVEY, PH.D.  
SUPERVISORY PATENT EXAMINER